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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,157	03/25/2004	Keith E. Jasperson	151P9958US02	7387

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IPLM GROUP, P.A.
POST OFFICE BOX 18455
MINNEAPOLIS, MN 55418

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,157	JASPERSON ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/14/04, 9/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 7/14/2004, 9/28/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: Table II, paragraphs 43, 45, and 46 are in need of correction. It appears that the last entry in Table II for the time frame of 22:00-24:00 hrs should be 70 not 105 as shown in Table II. This would make the total for the 24 hr time period 575 mg instead of 610 mg as now shown.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6, 9- are rejected under 35 U.S.C. 102(b) as being anticipated by Kraegen et al (4475901). Kraegen et al discloses a method of delivering a fluid

medication to a patient under direction of a medical professional, comprising the steps of: delivering said fluid medication to said patient through an implanted device continually at a basal rate (abstract, col 2, lns 45-54) and capable of delivering said fluid medication at an interval rate (abstract, col 2, lns 45-54) in each of a plurality of time slots over a specified period of time (col 5, lns 5-8, 33-35, col 6, lns4-19, col 7, lns 3-22, col 9, lns 52-65), said interval rate being different from said basal rate; controlling said basal rate and said interval rate at which said fluid medication is delivered to said patient; determining a total dose of said fluid medication to be delivered to said patient over said period of time based on said basal rate and said interval rate for each of said plurality of time slots (col 2, lns 45-col 3, lns 3; col 4, lns19-35; col 6, lns 8-15, 36-50, col 7, lns 3-65); and adjusting said basal rate to maintain said total dose (col 2, lns 45-col 3, lns 3; col 4, lns19-35; col 6, lns 8-15, 36-50, col 7, lns 3-65); wherein said total dose equals said maximum dose; wherein said interval rate may be programmed individually for each of said plurality of time slots (col 2, lns 45-col 3, lns 3; col 4, lns19-35; col 6, lns 8-15, 36-50, col 7, lns 3-65; wherein each of the time slots is capable of being programmed with an interval rate); wherein at least two of said plurality of time slots are of equal/unequal duration (col 2, lns 45-col 3, lns 3; col 4, lns19-35; col 6, lns 8-15, 36-50, col 7, lns 3-65; wherein the time period is fully capable of being equal or unequal by different control schedules); wherein said controller provides a graphical display of said interval rate in each of said plurality of time slots (115, 118); wherein said controller provides said graphical display to said medical professional (col 9, lns 1-19, 52-65).

5. Claims 1-4, 6, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Zalesky et al (5389078). Zalesky et al discloses a method of delivering a fluid medication to a patient under direction of a medical professional, comprising the steps of: delivering said fluid medication to said patient through an implanted device continually at a basal rate (abstract, Figs 4a-d, col 2, lns 57-64, col 4, lns 60-col 7, lns 4; wherein the continuous rate constitutes a basal rate) and capable of delivering said fluid medication at an interval rate (col 4, lns 60-col 7, lns 4; wherein the demand dose constitutes and interval rate) in each of a plurality of time slots over a specified period of time (col 4, lns 60-col 7, lns 4; wherein the demand dose is set at a rate change of time between times (ie 161,162), said interval rate being different from said basal rate; controlling said basal rate and said interval rate at which said fluid medication is delivered to said patient; determining a total dose of said fluid medication to be delivered to said patient over said period of time based on said basal rate and said interval rate for each of said plurality of time slots (col 4, lns 60-col 7, lns 4); and adjusting said basal rate to maintain said total dose (col 4, lns 60-col 7, lns 4; total rate 210). In reference to claims 2-4, 6, 9-11, see (col 4, lns 60-col 7, lns 4; wherein the total dose is the maximum dose – see also the lockout discussion in col 3, lns 64-67, col 4, lns 62-64; wherein the time slots are equal/unequal (Figs 3a, 3b); and wherein the graphical display is 50).

6. Claims 1-7, 9-10 rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub et al (2001/0037083). Hartlaub et al discloses a method of delivering a fluid

medication to a patient under direction of a medical professional, comprising the steps of: delivering said fluid medication to said patient through an implanted device continually at a basal rate ([0010]) and capable of delivering said fluid medication at an interval rate ([0010, 0030, 0032, 0037-0042]; wherein the additional bolus is programmed and specified by the patient) in each of a plurality of time slots over a specified period of time ([0010, 0030, 0032, 0037-0042]; wherein the patient is fully capable of programming the additional bolus and initiating treatment at any time; the Examiner notes that the applicant has not specified that the controlling of the basal rate and interval rates are performed by a programmable controller), said interval rate being different from said basal rate; controlling said basal rate and said interval rate at which said fluid medication is delivered to said patient; determining a total dose of said fluid medication to be delivered to said patient over said period of time based on said basal rate and said interval rate for each of said plurality of time slots ([0010, 0030, 0032, 0037-0042]); and adjusting said basal rate to maintain said total dose ([0010, 0030, 0032, 0037-0042]); wherein said total dose equals said maximum dose; wherein said interval rate may be programmed individually for each of said plurality of time slots (see above discussion with regards to patient initiations of interval rate); wherein at least two of said plurality of time slots are of equal/unequal duration ([0010, 0030, 0032, 0037-0042]); therein said period of time is a day and wherein said total dose is a daily dose ([0030]); wherein said controller provides a graphical display of said interval rate in each of said plurality of time slots (304); wherein said controller provides said graphical display to said medical professional (304).

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 1-11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 25-35 of copending Application No. 10/278769. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6599281; 6579280; 6010483; 5069668; 4559037; 4282872.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER